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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/960,557	10/31/1997	EUGENIO A. CEFALI	SD-50003USP6	6174

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1611	

NOTIFICATION DATE	DELIVERY MODE
03/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents_Abbott_Park@abbott.com
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Office Action Summary	Application No.	Applicant(s)	
	08/960,557	CEFALI ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12-14-07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30,32,34-36,38,40-42,44,46,62 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30,32,34-36,38,40-42,44,46,62 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-6-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt of amendment, remarks and declaration dated 12-14-07 and IDS dated 1-6-08 is acknowledged.

Claims 29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63 are pending in the instant application.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. However, it appears that there is a typographical error in the priority claim, where applicants refer to application number 08/818,974, now U.S. Patent No. 6,129,920, instead of application no. 08/814,974, which is now US .Patent 6,129,930. However, the above application is not related to the instant application and applicants are requested to correct the error.

In response to the amendment, the following rejections of record have been withdrawn:

3. Claims 29-36 and 38-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

4. Claims 1-5, 17, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating cholesterol disorders with an intermediate release composition comprising nicotinic acid, which exhibits a specific dissolution profile manufactured by wet granulation of hydroxypropyl methylcellulose, povidone and stearic acid, does not reasonably provide enablement for the claimed

method with any pharmaceutical delivery system so as to achieve the claimed in vitro dissolution.

5. Claims 29-36 and 38-61 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,268,181 to O'Neil et al (181).

The following rejections of record have been maintained:

6. **In response to the double patenting rejections applicants state that the rejection be held in abeyance until notification from the Examiner of allowable subject matter and that upon receipt of allowable subject matter, Applicants will take the necessary steps to remove this rejection. However, at this time there is no allowable subject matter and therefore the rejections have been maintained.**

7. In response to the rejection that Claims **29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63** are directed to an invention not patentably distinct from the claims 1-13 of U.S. Patent No. 6,080,428; claims 1-148 of U.S. Patent No. 6,129,920; claims 1-30 of U.S. Patent No. 6,469,035; claims 1-16 of U.S. Patent No. 6,406,715, claims 1-21 of U.S. Patent No. 6,746,691, claims 1-28 of U.S. Patent No. 6,818,229 and claims 1-12 of U.S. Patent No. 7,011,848, all of which are commonly assigned, applicants submit that the above application and all of the above listed patents are commonly owned (Exhibits A & B). However, the common assignee statement should state the patents are commonly owned at the time of the instant invention was made. Accordingly, the rejection has been maintained.

In response to the amendment, the following new rejection has been applied to the pending claims:

8. Claims **29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63** are rejected on the ground of nonstatutory obviousness- type double patenting as being unpatentable over claims 15-42, 58, 63, 64, 71-81 co-pending application no. 10/444,145. Although the conflicting claims are not identical, they are not patentably distinct from each other, the co-pending claims are directed to the method of treating hyperlipidemia with a similar composition as that of the instant application and further recite an amount of nicotinic acid that encompasses the claimed 1000 mg of nicotinic acid of the instant claims. Further, the copending claims also recite the same swelling agents that are also claimed in the instant dependant claims. It would have been within the scope of a skilled artisan at the time of the instant invention to prepare instant compositions from the co-pending compositions with an expectation to provide a treatment for hyperlipidemia, which is one of the cholesterol disorders. While copending claims do not recite the claimed intermediate release of the instant composition, the copending application encompasses composition with the claimed amount of nicotinic acid and therefore a skilled artisan would have expected to achieve the instant claimed release rates.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,126,145 to Evenstad et al ('145) or US 5,268,181 to O'Neil et al (181).

'145 teach sustained or controlled release tablets comprising 250, 500 or 750 mg niacin (col. 5, I1. 54-55). The tablets of '145 comprise 5-30 wt.% hydroxypropyl methylcellulose (HPMC) (col. 3, I1. 18-39), 2-5 wt.% binders (i.e. PVP, starch, gelatin, sucrose, lactose, methylcellulose, HPMC having binding properties and the like) (col. 3, I1. 40 through col. 4, I1. 12), 2-20 wt.% hydrophobic component (preferably stearic acid and hydrogenated vegetable oil) (col. 4, I1. 13 through col. 5, I1. 9), lubricants, dyes, fillers and extenders (col. 5, II. 10-36). '145 further teach that the dissolution profile of the tablets is 10-35% release in 2 hours after oral ingestion, 40-70% in 8 hours, and at least 90% in 24 hours (col. 5, I1. 66 through col. 6, H. 5).

Examiner notes that the above e common inventive entity i.e., Evanstad and O'Neil. The teachings of '181 have been described in the last action. '181 teach a composition comprising niacin in an amount as high as 750 mg (see examples), for the treatment of hyperlipidemia (abstract, col. 2). The composition is administered in the evening similar to the instant claims. '181 teach the same delivery system as that described in the instant claims i.e., HPMC, magnesium stearate etc (see examples). While the Example 1 of both references teach 750 mg of niacin but not 1000mg, both of

them teach the composition comprising niacin from as low as 250 mg to about 750 mg, for the same effect as claimed in the instant invention and therefore it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to choose the optimum amount of niacin so as to achieve a desired controlled release profile because '145 and '181 teach that the hydrophilic matrix system is dynamic system involving wetting, hydration and dissolution of the drug and can accommodate high amounts of soluble drugs (col.2).

Applicants' arguments as well as the declaration submitted by David Bova have been considered but not found persuasive. While the references '181 are no longer applied under 35 USC 102(b) or 102(e), the references are still applicable under the above section. The declaration submitted by Mr. Bova is not commensurate with the scope of the claims because the claims are now limited to 1000 mg of nicotinic acid as opposed to the 1500 mg formulations tested in Table II of the application. Further, both '181 and '145 recognize the sellable polymers of the instant claims as suitable matrix material for the wetting, hydration and dissolution of niacin such that a desired control over the release of niacin is achieved.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
March 2, 2008